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20

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,067	06/19/2001	Peter Jan Leonard Mario Quaedfleg	246152014600	1020

25225 7590 03/13/2006

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EXAMINER

FRONDA, CHRISTIAN L

ART UNIT PAPER NUMBER

1652

DATE MAILED: 03/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/869,067	Applicant(s) QUAEDFLIEG ET AL.	
	Examiner Christian L. Fronda	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 01/18 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1652

DETAILED ACTION

1. Claims 1 and 4-12 are pending and under consideration in this Office Action. The finality of the previous Office Action has been withdrawn in view of new rejections and new grounds of rejection.
2. The rejection of claim 3 under 35 U.S.C. 112, second paragraph, as being indefinite is moot in view of applicants' cancellation of claim 3 filed in the amendment dated 01/18/2006. This rejection has been withdrawn
3. The rejection of claims 1 and 4-12 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement has been withdrawn in view of applicants' and amendment filed on 01/18/2006.
4. The rejection of claims 1, 4-9, 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rajagopalan et al. (Biochemistry. 1997 Nov 11;36(45):13910-8) in view of applicants' and amendment filed on 01/18/2006.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
6. Claims 1 and 4-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
In claim 1, lines 6-7, the phrase "unprotected corresponding unprotected α -aminonitriles" renders the claim vague and indefinite. The meaning of the phrase is not clear, and it is not certain if applicants intended to recite the phrase "unprotected corresponding α -aminonitrile". Dependent claims 4-12 are also rejected because they do not correct the defect of claim 1. Appropriate correction is requested.

Art Unit: 1652

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1 and 4-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a process for preparing α -aminonitriles with enhanced optical purity from a mixture of chiral N-formylated α -aminonitriles using an *E.coli* peptide deformylase having a bivalent metal ion cofactor of Fe and containing the amino acid sequences of (i) HEXXH, (ii) EGCLS, and (iii) GXGXAAXQ; does not reasonably provide enablement for any other embodiment as recited in the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *re Wands* [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The *Wands* factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompass a process for preparing α -aminonitriles with enhanced optical purity from a mixture of chiral N-formylated α -aminonitriles using any acylase or peptide deformylase of any amino acid sequence and structure from any biological source.

The specification provides guidance and working examples for an *E.coli* peptide deformylase having a bivalent metal ion cofactor of Fe and containing the amino acid sequences of (i) HEXXH, (ii) EGCLS, and (iii) GXGXAAXQ; and a method using said *E.coli* peptide deformylase for deformylating *N*-formyl-valine aminonitrile, *N*-formyl -*m*-methoxyphenylalanine aminonitrile, and *N*-formyl -phenylalanine aminonitrile with increased optical purity (see Examples I-III). However, the specification does not provide guidance, prediction, and working examples for using any acylase or peptide deformylase of any amino acid sequence and structure from any biological source for the preparation of α -aminonitriles with enhanced optical purity from a mixture of chiral N-formylated α -aminonitriles.

Art Unit: 1652

Thus, an undue amount of trial and error experimentation must be preformed, where such experimentation involves searching and screening a vast number of biological sources for any acylase or peptide deformylase of any amino acid sequence and structure. Trial and error experimentation must then be performed to ascertain whether the acylase or peptide deformylase can be used in the preparation of α -aminonitriles with enhanced optical purity from a mixture of chiral N-formylated α -aminonitriles. General teaching regarding screening and searching for the recited acylase or peptide deformylase is not guidance for making the claimed invention.

The Examiner finds that one skilled in the art would require additional guidance, such as information regarding the specific acylase or peptide deformylase which can be used in the preparation of α -aminonitriles with enhanced optical purity from a mixture of chiral N-formylated α -aminonitriles. Without such a guidance, the amount of experimentation left to those skilled in the art to make and/or use the invention is undue and well outside of routine experimentation.

Amending the claims to recite a process for preparing α -aminonitriles with enhanced optical purity from a mixture of chiral N-formylated α -aminonitriles using an *E.coli* peptide deformylase having a bivalent metal ion cofactor of Fe and containing the amino acid sequences of (i) HEXXH, (ii) EGCLS, and (iii) GXGXAAXQ may overcome the rejection.

Conclusion

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).CLF

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TEKCHAND SAIDHA
PRIMARY EXAMINER